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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

OLEG NESTERENKO, Individually and on  
Behalf of All Others Similarly Situated,

Plaintiff,

v.

BOLT BIOTHERAPEUTICS, INC., RANDALL  
C. SCHATZMAN, WILLIAM P. QUINN, and  
EDITH PEREZ,

Defendants.

Case No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE  
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Plaintiff Oleg Nesterenko (“Plaintiff”), individually and on behalf of all others similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Bolt Biotherapeutics, Inc. (“Bolt” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet.

1 Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set  
2 forth herein after a reasonable opportunity for discovery.

3 **NATURE OF THE ACTION**

4 1. This is a federal securities class action on behalf of a class consisting of all persons  
5 and entities other than Defendants that purchased or otherwise acquired Bolt securities between  
6 February 5, 2021 and May 14, 2024, both dates inclusive (the “Class Period”), seeking to recover  
7 damages caused by Defendants’ violations of the federal securities laws and to pursue remedies  
8 under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and  
9 Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.  
10

11 2. Bolt, a clinical-stage biopharmaceutical company, engages in the development of  
12 immunotherapies for the treatment of cancer. The Company’s business model relies primarily on  
13 the success of its “Boltbody” pipeline of immuno-oncology product candidates. Bolt’s product  
14 pipeline includes the immune-stimulating antibody conjugate (“ISAC”) BDC-1001<sup>1</sup>, designed to  
15 target a tumor antigen known as human epidermal growth factor receptor 2 (“HER2”) that is often  
16 found in cancers such as breast and gastroesophageal cancer, as well as BDC-3042 and BDC-  
17 4182, programs “targeting the clinically validated cancer antigen Claudin 18.2.”  
18

19 3. Historically, Bolt’s lead asset was BDC-1001, which had pre-defined success  
20 criteria that included an overall response rate (“ORR”) efficacy threshold of at least 30% and,  
21 according to Bolt, purportedly “provide[d] a compelling example of the potential of Boltbody  
22 ISACs to address unmet medical needs in solid tumors” by “targeting HER2-expressing tumors  
23 and related metastatic disease, triggering their destruction by the innate and adaptive immune  
24 systems.”  
25

26  
27  
28 <sup>1</sup> In March 2024, Bolt announced that it had renamed BDC-1001 as trastuzumab imbotolimod.

1           4. Throughout the Class Period, Defendants made materially false and misleading  
2 statements regarding the Company's business, operations, and prospects. Specifically,  
3 Defendants made false and/or misleading statements and/or failed to disclose that: (i) BDC-1001  
4 was less effective than the Company had represented to investors and was in fact unlikely to meet  
5 its pre-defined success criteria; (ii) accordingly, Defendants overstated the clinical and/or  
6 commercial prospects of Bolt's product pipeline, on which the Company primarily relies to  
7 sustain its business model; (iii) all of the foregoing subjected the Company to a heightened risk  
8 of disruptive leadership transitions and substantial workforce reduction; and (iv) as a result, the  
9 Company's public statements were materially false and misleading at all relevant times.  
10

11           5. On May 14, 2024, issued a press release announcing that the Company would  
12 cease further development of BDC-1001 and focus resources on BDC-3042 and BDC-4182 upon  
13 determining that BDC-1001 failed to meet its pre-defined success criteria, that the Company's  
14 Chief Executive Officer ("CEO") Randall C. Schatzman ("Schatzman") and Chief Medical  
15 Officer ("CMO") Edith Perez ("Perez") would be moved into advisory roles, and that Bolt would  
16 be reducing its workforce by approximately 50%. In addition, following Bolt's announcement,  
17 multiple analysts downgraded the Company's stock, citing BDC-3042 and BDC-4182's  
18 questionable near-term commercial prospects and the departure of the Company's CEO and CMO  
19 as reasons for the downgrade.  
20

21           6. On this news, Bolt's stock price fell \$.49 per share, or 37.12%, to close at \$0.83  
22 per share on May 15, 2024.  
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24           7. As a result of Defendants' wrongful acts and omissions, and the precipitous  
25 decline in the market value of the Company's securities, Plaintiff and other Class members have  
26 suffered significant losses and damages.  
27  
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**JURISDICTION AND VENUE**

8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

10. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Bolt is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

11. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

**PARTIES**

12. Plaintiff, as set forth in the attached Certification, acquired Bolt securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Bolt is a Delaware corporation with principal executive offices located at 900 Chesapeake Drive, Redwood City, CA 94063. The Company's stock trades on the NASDAQ under the ticker symbol "BOLT".

14. Defendant Schatzman served as Bolt's CEO at all relevant times during the Class Period and currently serves in an advisory role at the Company.

1           15. Defendant William P. Quinn (“Quinn”) served as the Company’s Chief Financial  
2 Officer at all relevant times during the Class Period and currently serves as the Company’s CEO.

3           16. Defendant Perez served as the Company’s CMO at all relevant times during the  
4 Class Period and currently serves in an advisory role at the Company.

5           17. Defendants Schatzman, Quinn, and Perez are sometimes referred to herein as the  
6 “Individual Defendants.”  
7

8           18. The Individual Defendants possessed the power and authority to control the  
9 contents of Bolt’s SEC filings, press releases, and other market communications. The Individual  
10 Defendants were provided with copies of Bolt’s SEC filings and press releases alleged herein to  
11 be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent  
12 their issuance or to cause them to be corrected. Because of their positions with Bolt, and their  
13 access to material information available to them but not to the public, the Individual Defendants  
14 knew that the adverse facts specified herein had not been disclosed to and were being concealed  
15 from the public, and that the positive representations being made were then materially false and  
16 misleading. The Individual Defendants are liable for the false statements and omissions pleaded  
17 herein.  
18

19           19. Bolt and the Individual Defendants are collectively referred to herein as  
20 “Defendants.”  
21

## 22                           **SUBSTANTIVE ALLEGATIONS**

### 23                           **Background**

24           20. Bolt, a clinical-stage biopharmaceutical company, engages in the development of  
25 immunotherapies for the treatment of cancer. The Company’s business model relies primarily on  
26 the success of its “Boltbody” pipeline of immuno-oncology product candidates. Bolt’s product  
27  
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1 pipeline includes the ISAC BDC-1001, a program designed to target HER2, as well as BDC-3042  
2 and BDC-4182, programs “targeting the clinically validated cancer antigen Claudin 18.2.”

3 21. Historically, Bolt’s lead asset was BDC-1001, which had pre-defined success  
4 criteria that included an ORR efficacy threshold of at least 30% and, according to Bolt,  
5 purportedly “provide[d] a compelling example of the potential of Boltbody ISACs to address  
6 unmet medical needs in solid tumors” by “targeting HER2-expressing tumors and related  
7 metastatic disease, triggering their destruction by the innate and adaptive immune systems.”  
8

9 **Materially False and Misleading Statements Issued During the Class Period**

10 22. The Class Period begins on February 5, 2021, when Bolt began trading on the  
11 NASDAQ following the completion of its initial public offering (“IPO”). In connection with the  
12 IPO, Bolt filed a registration statement with the SEC on Form S-1 (the “Registration Statement”)  
13 which, in providing an overview of the business, stated, in relevant part:  
14

15 We are a clinical-stage immuno-oncology company developing tumor-  
16 targeted therapies that leverage the power of the innate and adaptive immune  
17 systems. Our proprietary Boltbody Immune-Stimulating Antibody Conjugate, or  
18 ISAC, approach uses immunostimulants to engage and activate myeloid cells,  
19 including macrophages and dendritic cells, that directly kill tumor cells via  
20 phagocytosis and expose tumor neoantigens to the adaptive immune system. This  
21 leads to recruitment of cytotoxic T cells and additional tumor-killing myeloid cells  
22 thereby converting immunologically “cold” tumors to “hot” tumors. We believe  
23 that this process leads to the development of systemic immunological memory with  
24 epitope spreading to neoantigens that is critical to achieving a long-term anti-tumor  
25 response. Our lead product candidate BDC-1001 is a human epidermal growth  
26 factor receptor 2, or HER2, Boltbody ISAC comprised of a HER2-targeting  
27 biosimilar of trastuzumab conjugated to one of our proprietary TLR7/8 agonists,  
28 for the treatment of patients with HER2-expressing solid tumors, including those  
with HER2-low tumors. We have demonstrated robust single agent anti-tumor  
activity in multiple preclinical models, including elimination of large tumors (~500  
mm<sup>3</sup>), as well as tumors that are refractory to trastuzumab or ado-trastuzumab  
emtansine. In our preclinical safety studies, BDC-1001 was well tolerated and no  
adverse safety signals were observed. We believe these findings are encouraging  
for the therapeutic potential of BDC-1001.

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Our lead product candidate, BDC-1001, is currently in clinical development for the treatment of patients with HER2-expressing solid tumors, including those with HER2-low tumors. *We have designed BDC-1001 as a Boltbody ISAC comprised of a HER2-targeting biosimilar trastuzumab conjugated to one of our proprietary TLR7/8 agonists to maximize the potential anti-tumor response. Through our preclinical studies in mice, we have demonstrated that systemic administration of HER2 Boltbody ISACs exhibited localized immune activation that resulted in single agent activity that eliminated large or refractory tumors, and generated immunological memory against cancers with epitope spreading. Furthermore, preclinical data showed anti-tumor activity against established tumors resistant to trastuzumab and ado-trastuzumab emtansine, and immunological memory providing protection against tumor cells that no longer express the HER2 antigen. Our observed preclinical anti-tumor response coupled with a lack of adverse safety signals in our non-human primate toxicology studies leads us to believe that BDC-1001 offers the potential for long-term and meaningful response for patients with HER2-expressing cancers, including HER2-low tumors.*<sup>2</sup>

23. Further, in discussing the Company's strategy, the Registration Statement stated, in relevant part:

Our goal is to become a leading immuno-oncology company, leveraging our myeloid biology expertise and proprietary Boltbody ISAC approach to discover, develop and commercialize transformative treatments to address key unmet medical needs in cancer. The key components of our strategy are to:

- **Leverage our Boltbody ISAC approach and myeloid expertise to develop our pipeline of immune-activating therapies.** Our expertise in myeloid biology and immuno-oncology has led us to research various tumor antigens across solid tumors where significant unmet medical needs remain. Our expertise in medicinal chemistry and mAb engineering and our ability to modulate TLR linker-payloads allow us to optimize the therapeutic profile of our product candidates for any particular tumor antigen as part of our research and discovery efforts to produce durable anti-tumor responses. We believe that our approach is applicable to a broad spectrum of tumor-associated antigens expressed on cancers, including those that are refractory to existing therapies.
- **Rapidly advance the development of our lead Boltbody ISAC product candidate, BDC-1001, for the treatment of patients with HER2-expressing cancers.** BDC-1001 is currently in an ongoing Phase 1/2 clinical trial for the treatment of patients with HER2-expressing solid tumors. Based on our promising preclinical activity, BDC-1001 has the

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<sup>2</sup> All emphases included herein are added unless otherwise indicated.



potential to be effective both as a monotherapy and in combination with existing therapies for patients with HER2-expressing solid tumors. While currently approved HER2-targeting agents are important and effective treatment options for some patients with HER2-expressing solid tumors, a large percentage of patients do not respond to these therapies, develop tumor progression after initial response or are not indicated for current HER2-targeting therapies. These sizable patient populations do not have adequate treatment options available to them. Therefore, we intend to rapidly advance development of BDC-1001 across multiple HER2-expressing cancers, including in both HER2-expressing and certain HER2-low cancers.

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- **Continue to invest in our myeloid expertise and Boltbody ISAC approach to explore the full potential of our targeted immunotherapies for the treatment of cancer.** Our expertise, rigor and unbiased data-driven approach may lead to additional research and discovery programs that are complementary or independent of our Boltbody ISAC approach and our growing library of innate immune stimulators. Our research and discovery efforts are exploring additional immune agonists for the Boltbody ISAC approach as well as identifying novel targets in tumor-associated myeloid cells that can be targeted for anti-tumor outcomes. We believe such agents have the potential to reprogram tumor-supportive macrophages into tumor-destructive macrophages to elicit a productive anti-tumor immune response. This approach could potentially provide an avenue to further develop precision medicine with an immune modulator.

24. On March 31, 2021, Bolt issued a press release announcing the Company's Q4 and full year 2020 financial results. The press release stated, in relevant part:

"Our upsized Initial Public Offering, which we completed in February 2021, leaves us in a strong financial position to execute on our vision of developing this new class of immuno-oncology products to help patients. We continue to enroll patients in the dose escalation part of our Phase 1/2 trial for our lead candidate, BDC-1001, for the treatment of patients with HER2-expressing solid tumors. We reported preliminary clinical results from an initial 20 patients at a data cutoff of January 29, 2021, which demonstrated 4 patients with stable disease and one patient with a confirmed partial response. We're looking forward to completing the dose escalation and initiating both the monotherapy Phase 2 dose expansions part and the combination studies with an anti-PD-1 antibody part later in 2021," said [Defendant] Schatzman[.] "We continue to progress our broader pipeline of targeted immunotherapies derived from our Boltbody™ ISAC platform, a novel technology that can be applied across a diverse range of tumor targets and has the potential to enable cancer patients to generate immunological memory against their own tumors. We plan to advance our second Boltbody ISAC BDC-2034, which targets the cancer antigen CEA, into the clinic in 2022."



25. That same day, Bolt filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operational results for the year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K contained substantively similar descriptions of the Company's business and strategy as discussed, *supra*, in ¶¶ 22-23.

26. Appended to the 2020 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Schatzman and Quinn, attesting that "the information contained in the [2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

27. On May 13, 2021, Bolt issued a press release announcing the Company's Q1 2021 financial results. The press release stated, in relevant part:

"Our successful IPO in the first quarter of 2021 places us in a position of strength to deliver on value-creating milestones in 2021 and 2022. We continue to advance our Phase 1/2 trial for our lead candidate, BDC-1001, for the treatment of patients with HER2-expressing solid tumors. We look forward to completing the monotherapy dose escalation and initiating the monotherapy Phase 2 dose expansion cohorts as well as the evaluation of combining BDC-1001 with an anti-PD-1 antibody later in 2021," said [Defendant] Schatzman[.] "Beyond BDC-1001, we continue to advance our pipeline and are on track to initiate clinical trials for CEA-targeted ISAC BDC-2034 in 2022 and we expect to designate our third clinical candidate later this year."

28. On August 12, 2021, Bolt issued a press release announcing the Company's Q2 2021 financial results. The press release stated, in relevant part:

"We continue to build strong momentum with our business strategy and remain on target for a BDC-1001 Phase 1/2 clinical data update later this year," said [Defendant] Schatzman[.] "Our recently announced Genmab collaboration expands our proprietary Boltbody platform into novel bispecific ISAC applications, while fortifying our strong cash position. Furthermore, our CEA-targeted candidate BDC-2034 made steady progress towards an IND filing that is expected next year. I am proud of the passionate and experienced team we have assembled at Bolt, including recent additions to our leadership, who share our commitment to advancing targeted immuno-oncology therapies that will benefit patients with cancer."

29. On November 9, 2021, Bolt issued a press release announcing the Company's Q3 2021 financial results. The press release stated, in relevant part:

1 "This quarter was notable for the significant progress we made across our entire  
2 pipeline of novel ISACs and with successful partnering of Bolt's pioneering  
3 technology. We continued robust enrollment of the dose escalation portion of the  
4 BDC-1001 Phase 1/2 trial and we anticipate initiation of the combination dose  
5 escalation with Opdivo by year-end," said [Defendant] Schatzman[.] "We look  
6 forward to providing an update on our progress with BDC-1001 at the ESMO  
7 Immuno-Oncology Congress in December."

8 30. On January 6, 2022, Bolt issued a press release entitled "Bolt Biotherapeutics  
9 Doses First Patient with BDC-1001 in Combination with OPDIVO® (nivolumab) in Ongoing  
10 Phase 1/2 Clinical Trial for the Treatment of HER2-Expressing Solid Tumors." The press release  
11 stated, in relevant part:

12 "We are excited to evaluate BDC-1001 in combination with nivolumab, a leading  
13 PD-1 checkpoint inhibitor. Pairing BDC-1001's mechanism of action with the  
14 checkpoint inhibitor approach has the potential to yield a stronger, targeted  
15 modulation of the immune system. Initial safety and early efficacy findings  
16 reported from the ongoing monotherapy arm of the Phase 1/2 clinical trial make  
17 BDC-1001 a potentially promising candidate for the treatment of patients with  
18 HER2-expressing solid tumors," said [Defendant] Perez[.] "In the early clinical  
19 development of BDC-1001, our strategy is to follow the science, elucidating how  
20 this novel approach to engaging a patient's immune system can eliminate tumors  
21 not addressed by currently available therapies. We look forward to investigating  
22 BDC-1001 in this first combination arm as we also continue investigation of its  
23 single-agent activity."

24 31. On March 30, 2022, Bolt issued a press release announcing the Company's Q4  
25 and full year 2021 results. The press release stated, in relevant part:

26 "In 2021, we demonstrated for the first time that our HER2-targeting Boltbody  
27 ISAC can increase myeloid cell infiltration and repolarize macrophages in the  
28 tumor microenvironment, and thereby, established proof of mechanism for our  
pioneering Boltbody ISAC platform. In our Phase 1/2 study, BDC-1001 was well  
tolerated at all dose levels tested with no dose-limiting toxicities. At the lower dose  
levels evaluated to date, we have seen stable disease in multiple different tumor  
types and a partial response that has now persisted for more than 60 weeks," said  
Randall C. Schatzman, Ph.D., Chief Executive Officer of Bolt Biotherapeutics.  
"We continue to explore dose levels expected to achieve our targeted higher drug  
exposures, and look forward to determining the recommended Phase 2 dose for  
BDC-1001 as monotherapy and in combination with Opdivo."

32. That same day, Bolt filed an Annual Report on Form 10-K with the SEC, reporting  
the Company's financial and operational results for the year ended December 31, 2021 (the "2021

10-K”). The 2021 10-K contained substantively similar descriptions of the Company’s business and strategy as discussed, *supra*, in ¶¶ 22-23 and, regarding those same topics, further stated, in relevant part:

Our expertise in myeloid cell biology also forms the foundation for additional, innovative ways to target the immune activation that complement our Boltbody ISAC platform. ***An example of this approach is BDC-3042, our Dectin-2 agonist antibody program.*** BDC-3042 is being developed to repolarize critical cells in the tumor microenvironment by targeting cell-surface receptors on macrophages. Dectin-2 agonism results in these tumor-associated macrophages (TAMs) changing to the tumor-destructive M1 phenotype, away from the M2 phenotype, which suppresses immune responses and supports tumor growth.

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### Strategy

Our goal is to become a leading immuno-oncology company, leveraging our myeloid biology expertise and proprietary Boltbody ISAC approach to discover, develop and commercialize transformative treatments to address key unmet medical needs in cancer. The key components of our strategy are to:

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- **Expediently advance our pipeline focused on additional promising targets including CEA and Dectin-2.** Our robust pipeline includes BDC-2034, an ISAC targeting CEA and BDC-3042, an antibody targeting Dectin-2. ***These programs represent additional opportunities to demonstrate our expertise in myeloid biology.*** We target myeloid cells in the targeted tumor microenvironment to initiate robust innate and adaptive immune responses. We believe that this differentiated approach could improve the lives of patients by producing durable anti-tumor responses. We expect BDC-2034 to enter the clinic in 2022, and BDC-3042 to enter the clinic in 2023.

33. Appended to the 2021 10-K as exhibits were signed certifications pursuant to SOX by Defendants Schatzman and Quinn, attesting that “the information contained in the [2021 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

34. On May 12, 2022, Bolt issued a press release announcing the Company’s Q1 2022 financial results. The press release stated, in relevant part:

1 “Our lead program, BDC-1001, for patients with HER2-expressing solid tumors is  
2 on track and we expect to complete both our monotherapy and combination dose  
3 escalation arms and select a recommended Phase 2 dose in the second half of 2022,”  
4 said [Defendant] Schatzman[.] “We continue to apply our expertise in myeloid  
5 biology to advance our diversified pipeline of novel Boltbody ISACs and our first-  
6 in-class Dectin-2 agonist antibody program. Our strong cash position and multiple  
7 collaborations with leading therapeutic antibody companies are expected to provide  
8 us with the funding to achieve key clinical milestones with our most promising  
9 candidates in a cash-efficient manner.”

10 35. On August 10, 2022, Bolt issued a press release announcing the Company’s Q2  
11 2022 financial results. The press release stated, in relevant part:

12 “The second quarter was one of continued progress, highlighted by steady clinical  
13 enrollment in our BDC-1001 monotherapy and combination dose-escalation  
14 studies. While we are fortunate to be operating from a position of financial strength,  
15 we have implemented a pipeline prioritization and new capital allocation initiative  
16 focused on advancing BDC-1001 and BDC-3042, two drug candidates that we  
17 believe have high potential to benefit patients,” said [Defendant] Schatzman[.] “We  
18 are winding down spending on BDC-2034, pausing other early-stage research  
19 programs, and prioritizing ISAC programs that bring forward the latest generation  
20 of our ISAC technology – including our collaboration programs. The combination  
21 of these strategic initiatives extends our expected cash runway an additional two  
22 years through 2025.”

23 36. On November 10, 2022, Bolt issued a press release announcing the Company’s Q3  
24 2022 financial results. The press release stated, in relevant part:

25 “In the third quarter, our clinical development team advanced BDC-1001 for the  
26 treatment of patients with HER2-expressing solid tumors through dose-escalation  
27 monotherapy and combination studies with Opdivo while exploring biweekly and  
28 weekly dosing schedules. We look forward to announcing topline data and our  
recommended Phase 2 dose for the monotherapy and combination dose-expansion  
trials during the first quarter of 2023, with full data to be presented at an upcoming  
scientific conference,” said [Defendant] Schatzman[.]

“We continue to make strong progress with our proprietary BDC-3042 program,  
which is progressing through IND-enabling activities supporting initiation of  
clinical studies in 2023, and our collaboration programs. Our work with strategic  
partners on ISAC pipeline programs positions Bolt to continuously innovate new  
targeted immunotherapies with the potential to improve the treatment of cancer.[”]

37. On March 29, 2023, Bolt issued a press release announcing the Company’s Q4  
and full year 2022 financial results. The press release stated, in relevant part:

1 “We believe the BDC-1001 Phase 1 results validate our Boltbody™ ISAC  
2 approach. Our design decisions enable us to deliver potent immune-stimulating  
3 antibody conjugates that can achieve positive clinical responses with acceptable  
4 tolerability, thereby, decoupling anti-tumor activity from the systemic safety issues  
5 that others have encountered. We are advancing into a thoughtfully designed,  
6 focused Phase 2 program evaluating BDC-1001 in patients with four different types  
7 of HER2-positive solid tumors where there remains important unmet medical  
8 need,” said [Defendant] Schatzman[.]

9 38. That same day, Bolt filed an Annual Report on Form 10-K with the SEC, reporting  
10 the Company’s financial and operational results for the year ended December 31, 2022 (the “2022  
11 10-K”). The 2022 10-K contained substantively similar descriptions of the Company’s business  
12 and strategy as discussed, *supra*, in ¶¶ 22-23 and 32.

13 39. Appended to the 2022 10-K as exhibits were signed certifications pursuant to SOX  
14 by Defendants Schatzman and Quinn, attesting that “the information contained in the [2022 10-  
15 K] fairly presents, in all material respects, the financial condition and results of operations of the  
16 Company.”

17 40. On May 11, 2023, Bolt issued a press release announcing the Company’s Q1 2023  
18 financial results. The press release stated, in relevant part:

19 “We are pleased to be advancing our lead Boltbody™ ISAC, BDC-1001, into a  
20 broader Phase 2 program in four different HER2-positive solid tumor types,  
21 following the recent positive topline results from our Phase 1 dose-escalation trial.  
22 We are looking forward to presenting a comprehensive dataset at ASCO from this  
23 first-in-human study, in which BDC-1001 achieved target drug exposure levels,  
24 was well tolerated from a safety perspective and demonstrated objective clinical  
25 responses and long-term durability both as a single agent and in combination with  
26 nivolumab,” said [Defendant] Schatzman[.] “As we prepare for Phase 2 studies in  
27 the U.S. and internationally, we look forward to investigating the benefits of BDC-  
28 1001 and our novel ISAC mechanism to aid HER2-positive cancer patients who are  
not benefitting from current therapeutic options. Additionally, the Bolt team is  
excited to be advancing our next program, BDC-3042, a proprietary Dectin-2  
agonist antibody, into the clinic later this year.”

41. On May 25, 2023, Bolt issued a press release entitled “Bolt Biotherapeutics  
Highlights Comprehensive Clinical Data from Phase 1 Dose-Escalation Trial of BDC-1001 as  
Monotherapy and in Combination with Nivolumab in HER2-Expressing Tumors at 2023 ASCO

Annual Meeting.” The press release quoted Defendant Perez as stating, in relevant part, “BDC-1001 has demonstrated a favorable safety profile and encouraging efficacy including multiple objective responses and long-term stable disease, as well as biomarker evidence of immune activation that support our ISAC mechanism of action,” and “[f]urthermore, these data support the initiation of our Phase 2 clinical program in four HER2-positive tumor types this year.”

42. On August 3, 2023, Bolt issued a press release entitled “Bolt Biotherapeutics Initiates Phase 2 Clinical Studies of BDC-1001 in Patients With HER2-Positive Cancer.” The press release stated, in relevant part:

“This is an important milestone for our company that builds on the positive signal of monotherapy activity that we observed in the Phase 1 portion of the study,” said [Defendant] Perez[.] “Despite considerable advances in anti-cancer therapy, HER2-positive tumors remain difficult to treat, and new therapeutic options are urgently needed. Our ISAC platform brings a novel mechanism with the potential to address refractory and recurrent disease to the treatment of HER2+ cancers and BDC-1001 has demonstrated promise. We are committed to advancing this study for the benefit of the many patients in need.”

43. On August 7, 2023, Bolt issued a press release announcing the Company’s Q2 2023 financial results. The press release stated, in relevant part:

“We have extended our leadership position in immunotherapy as the first company to initiate a Phase 2 program for an ISAC,” said [Defendant] Schatzman[.] “The FDA has also cleared the IND for BDC-3042, the first and only program targeting Dectin-2 with an agonist antibody. This is our second successful IND and we expect to begin this first-in-human clinical trial later this year. We presented positive data at ASCO and look forward to presenting more data at ESMO and other upcoming major medical meetings. Our team is highly motivated by all of this positive momentum and the opportunities for us to make a difference for cancer patients.”

“The data in the Phase 1 dose-escalation trial of BDC-1001 included durable objective clinical responses and a favorable safety profile. Importantly, these data provide clinical validation of our Boltbody™ ISAC approach, which has the potential to deliver a novel mechanism for the treatment of HER2-positive cancers and shows promise for patients who are resistant to current therapies on the market.”



1           44.     On September 28, 2023, Bolt issued a press release entitled “Bolt Biotherapeutics  
2     Receives Orphan Drug Designation for BDC-1001 for Treatment of Gastric Cancers.” The press  
3     release stated, in relevant part:

4           “Receiving Orphan Drug Designation from the FDA is an important step forward  
5     in the development of BDC-1001 and reinforces the potential of BDC-1001 to  
6     address unmet needs for patients with gastric cancers,” said [Defendant] Perez[.]  
7     “Our Boltbody™ ISAC platform is the only one with emerging clinical validation,  
8     and we are working diligently to advance our ongoing Phase 2 program. In addition  
9     to gastric cancer, we are also evaluating BDC-1001 in three other tumor types with  
   significant unmet medical need: HER2-positive breast, colorectal, and endometrial  
   cancers. We look forward to advancing BDC-1001 in clinical development and  
   bringing this novel immunotherapy to patients in need of further treatment options.”

10          45.     On November 9, 2023, Bolt issued a press release announcing the Company’s Q3  
11     2023 financial results. The press release stated, in relevant part:

12           “During the quarter, we continued to advance our proprietary clinical stage  
13     development programs, BDC-1001 and BDC-3042,” said [Defendant]  
14     Schatzman[.] “Updated Phase 1 data on BDC-1001 presented at this year’s ESMO  
15     Congress demonstrated improved efficacy, including our first complete response,  
16     and longer durability. We also recently received Orphan Drug Designation from  
   the FDA for BDC-1001 in gastric cancers, one of the four types of cancer we are  
   exploring in our BDC-1001 Phase 2 program. We look forward to presenting initial  
   data from these Phase 2 trials in 2024.”

17           “In addition, we administered BDC-3042 to the first patient in our first-in-human  
18     Phase 1/2 clinical study evaluating BDC-3042 in patients with six different types  
19     of solid tumors. As we approach the end of the year, we are encouraged by the  
20     continued progress in our research and clinical studies and look forward to  
   generating breakthroughs for patients in need of new treatment options that work  
   with the person’s body, not against it.”

21          46.     On December 5, 2023, Bolt issued a press release entitled “Bolt Biotherapeutics  
22     Enrolls First Patient in Phase 2 Clinical Study Evaluating BDC-1001 in Patients with HER2-  
23     Positive Breast Cancer Previously Treated with Enhertu®.” The press release quoted Defendant  
24     Perez as stating, in relevant part, “[p]atients with HER2-positive breast cancer who progress after  
25     Enhertu have few therapeutic options,” and “BDC-1001 has a unique mechanism of action  
26     27  
28



1 compared to available agents, mobilizing the patient's immune system to fight cancer. This  
2 provides scientific and clinical rationale for this new study."

3 47. On March 21, 2024, Bolt issued a press release announcing the Company's Q4  
4 and full year 2023 financial results. The press release quoted Defendant Schatzman stating, in  
5 relevant part, "[w]e made substantial progress advancing our two proprietary clinical-stage  
6 development programs in 2023," and "[w]e have now administered BDC-1001, which we have  
7 renamed trastuzumab imbotolimod, to patients in all five of the Phase 2 cohorts. BDC-3042 also  
8 continues to advance, and has now entered the fourth dose escalation cohort without a dose-  
9 limiting toxicity. Both clinical programs are on track and we look forward to providing updates  
10 later this year."

12 48. That same day, Bolt filed an Annual Report on Form 10-K with the SEC, reporting  
13 the Company's financial and operational results for the year ended December 31, 2023 (the "2023  
14 10-K"). The 2023 10-K contained substantively similar descriptions of the Company's business  
15 and strategy as discussed, *supra*, in ¶¶ 22-23 and 32.

17 49. Appended to the 2023 10-K as exhibits were signed certifications pursuant to SOX  
18 by Defendants Schatzman and Quinn, attesting that "the information contained in the [2023 10-  
19 K] fairly presents, in all material respects, the financial condition and results of operations of the  
20 Company."

22 50. The statements referenced in ¶¶ 22-49 were materially false and misleading  
23 because Defendants made false and/or misleading statements, as well as failed to disclose material  
24 adverse facts about the Company's business, operations, and prospects. Specifically, Defendants  
25 made false and/or misleading statements and/or failed to disclose that: (i) BDC-1001 was less  
26 effective than the Company had represented to investors and was in fact unlikely to meet its pre-  
27 defined success criteria; (ii) accordingly, Defendants overstated the clinical and/or commercial  
28

prospect of Bolt's product pipeline, on which the Company primarily relies to sustain its business model; (iii) all of the foregoing subjected the Company to a heightened risk of disruptive leadership transitions and substantial workforce reduction; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

### **The Truth Emerges**

51. On May 14, 2024, Bolt issued a press release entitled "Bolt Biotherapeutics Reports First Quarter 2024 Results, Announces Strategic Pipeline Prioritization and Changes to Leadership Team." The press release stated, in relevant part:

Bolt [. . .] today reported financial results for the first quarter ended March 31, 2024 and announced a strategic prioritization as well as changes to its leadership team. The company will focus its pipeline on its first-in-class proprietary agonist antibody targeting Dectin-2 and its next-generation Boltbody™ ISAC programs, continue to support its collaborations with Genmab and Toray, and reduce its workforce by approximately 50%. This will extend cash runway into the second half of 2026.

As part of this refocusing, [Defendant] Quinn has been appointed [CEO]. Grant Yonehiro has been promoted to Chief Operating Officer, Dawn Colburn, Pharm.D. has been promoted to Senior Vice President, Clinical Development. Michael Alonso, Ph.D. has been promoted to Senior Vice President, Research and Sarah Nemec is being appointed Principal Accounting Officer.

"At Bolt, we set a high bar for advancing our programs, and while BDC-1001 provided clinical validation for the ISAC mechanism, ***it did not meet our high bar for advancement.*** With limited resources, we want to focus those resources on the best product candidates. Our Boltbody™ ISAC technology platform continues to improve and our next-gen ISACs have outperformed cytotoxic ADCs in our preclinical studies. The increased activity of the next-gen Boltbody™ ISACs is opening the door to tumor targets with lower expression, while maintaining design choices that prioritize safety. ***With this in mind, we have decided to discontinue all BDC-1001 development and focus resources on BDC-3042 and BDC-4182,*** our next-gen ISAC targeting the clinically validated cancer antigen Claudin 18.2," said [Defendant] Quinn[.] "We believe that BDC-3042, a first-in-class agonist antibody that reawakens myeloid cells to attack tumor cells, has broad potential across many tumor types. We've seen encouraging safety to date in our Phase 1 dose escalation study of BDC-3042 and are excited about the very strong preclinical data for BDC-4182. We believe focusing on these programs will deliver significant value to shareholders. In conjunction, we are streamlining our operations to align resources and extend our cash runway to support these programs through key value inflection points."

52. Following Bolt's announcement, multiple analysts, including *Stifel*, *Guggenheim*, and *Leerink Partners* downgraded the Company's stock. Specifically, *Stifel* downgraded the Company to Hold from Buy and lowered its price target to \$1.50 from \$6.00 per share, noting a challenging catalyst path for the Company in the near term, and argued that a Phase 1 safety/enrollment update expected for BDC-3042 in the first-half of 2024 "is unlikely to prove narrative-changing," while BDC-4182 is set to enter the clinic in 2025 against a difficult competitive backdrop. Similarly, *Guggenheim* downgraded Bolt's stock to Neutral from Buy and removed the Company's price target, citing the departure of Defendants Schatzman and Perez and noting the lack of clarity regarding the prospects of BDC-3042 and BDC-4182. Finally, *Leerink Partners* downgraded the Company's stock to Market Perform from Outperform, lowering the price target to \$1.00 from \$3.00 per share, and wrote that BDC-3042 and BDC-4182 "are at the high end of risk, given novelty and early nature of development[.]"

53. On this news, Bolt's stock price fell \$.49 per share, or 37.12%, to close at \$0.83 per share on May 15, 2024.

54. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

### **SCIENTER ALLEGATIONS**

55. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

**PLAINTIFF'S CLASS ACTION ALLEGATIONS**

56. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Bolt securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

57. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Bolt securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Bolt or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

58. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

59. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

60. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Bolt;
- whether the Individual Defendants caused Bolt to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Bolt securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

61. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

62. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Bolt securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Bolt securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

63. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

64. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

### **COUNT I**

#### **(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)**

65. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

66. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

67. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state

1 material facts necessary in order to make the statements made, in light of the circumstances under  
2 which they were made, not misleading; and employed devices, schemes and artifices to defraud  
3 in connection with the purchase and sale of securities. Such scheme was intended to, and,  
4 throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other  
5 Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Bolt  
6 securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise  
7 acquire Bolt securities and options at artificially inflated prices. In furtherance of this unlawful  
8 scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth  
9 herein.  
10

11 68. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the  
12 Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly  
13 and annual reports, SEC filings, press releases and other statements and documents described  
14 above, including statements made to securities analysts and the media that were designed to  
15 influence the market for Bolt securities. Such reports, filings, releases and statements were  
16 materially false and misleading in that they failed to disclose material adverse information and  
17 misrepresented the truth about Bolt's finances and business prospects.  
18

19 69. By virtue of their positions at Bolt, Defendants had actual knowledge of the  
20 materially false and misleading statements and material omissions alleged herein and intended  
21 thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants  
22 acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose  
23 such facts as would reveal the materially false and misleading nature of the statements made,  
24 although such facts were readily available to Defendants. Said acts and omissions of Defendants  
25 were committed willfully or with reckless disregard for the truth. In addition, each Defendant  
26  
27  
28



1 knew or recklessly disregarded that material facts were being misrepresented or omitted as  
2 described above.

3 70. Information showing that Defendants acted knowingly or with reckless disregard  
4 for the truth is peculiarly within Defendants' knowledge and control. As the senior managers  
5 and/or directors of Bolt, the Individual Defendants had knowledge of the details of Bolt's internal  
6 affairs.  
7

8 71. The Individual Defendants are liable both directly and indirectly for the wrongs  
9 complained of herein. Because of their positions of control and authority, the Individual  
10 Defendants were able to and did, directly or indirectly, control the content of the statements of  
11 Bolt. As officers and/or directors of a publicly-held company, the Individual Defendants had a  
12 duty to disseminate timely, accurate, and truthful information with respect to Bolt's businesses,  
13 operations, future financial condition and future prospects. As a result of the dissemination of the  
14 aforementioned false and misleading reports, releases and public statements, the market price of  
15 Bolt securities was artificially inflated throughout the Class Period. In ignorance of the adverse  
16 facts concerning Bolt's business and financial condition which were concealed by Defendants,  
17 Plaintiff and the other members of the Class purchased or otherwise acquired Bolt securities at  
18 artificially inflated prices and relied upon the price of the securities, the integrity of the market  
19 for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.  
20

21 72. During the Class Period, Bolt securities were traded on an active and efficient  
22 market. Plaintiff and the other members of the Class, relying on the materially false and  
23 misleading statements described herein, which the Defendants made, issued or caused to be  
24 disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares  
25 of Bolt securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff  
26 and the other members of the Class known the truth, they would not have purchased or otherwise  
27  
28

1 acquired said securities, or would not have purchased or otherwise acquired them at the inflated  
2 prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class,  
3 the true value of Bolt securities was substantially lower than the prices paid by Plaintiff and the  
4 other members of the Class. The market price of Bolt securities declined sharply upon public  
5 disclosure of the facts alleged herein to the injury of Plaintiff and Class members.  
6

7 73. By reason of the conduct alleged herein, Defendants knowingly or recklessly,  
8 directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5  
9 promulgated thereunder.

10 74. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and  
11 the other members of the Class suffered damages in connection with their respective purchases,  
12 acquisitions and sales of the Company's securities during the Class Period, upon the disclosure  
13 that the Company had been disseminating misrepresented financial statements to the investing  
14 public.  
15

## 16 **COUNT II**

### 17 **(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)**

18 75. Plaintiff repeats and re-alleges each and every allegation contained in the  
19 foregoing paragraphs as if fully set forth herein.  
20

21 76. During the Class Period, the Individual Defendants participated in the operation  
22 and management of Bolt, and conducted and participated, directly and indirectly, in the conduct  
23 of Bolt's business affairs. Because of their senior positions, they knew the adverse non-public  
24 information about Bolt's misstatement of income and expenses and false financial statements.

25 77. As officers and/or directors of a publicly owned company, the Individual  
26 Defendants had a duty to disseminate accurate and truthful information with respect to Bolt's  
27  
28

1 financial condition and results of operations, and to correct promptly any public statements issued  
2 by Bolt which had become materially false or misleading.

3 78. Because of their positions of control and authority as senior officers, the Individual  
4 Defendants were able to, and did, control the contents of the various reports, press releases and  
5 public filings which Bolt disseminated in the marketplace during the Class Period concerning  
6 Bolt's results of operations. Throughout the Class Period, the Individual Defendants exercised  
7 their power and authority to cause Bolt to engage in the wrongful acts complained of herein. The  
8 Individual Defendants, therefore, were "controlling persons" of Bolt within the meaning of  
9 Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct  
10 alleged which artificially inflated the market price of Bolt securities.  
11

12 79. Each of the Individual Defendants, therefore, acted as a controlling person of Bolt.  
13 By reason of their senior management positions and/or being directors of Bolt, each of the  
14 Individual Defendants had the power to direct the actions of, and exercised the same to cause,  
15 Bolt to engage in the unlawful acts and conduct complained of herein. Each of the Individual  
16 Defendants exercised control over the general operations of Bolt and possessed the power to  
17 control the specific activities which comprise the primary violations about which Plaintiff and the  
18 other members of the Class complain.  
19

20 80. By reason of the above conduct, the Individual Defendants are liable pursuant to  
21 Section 20(a) of the Exchange Act for the violations committed by Bolt.  
22

23 **PRAYER FOR RELIEF**

24 **WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

25 A. Determining that the instant action may be maintained as a class action under Rule  
26 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;  
27  
28

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

**DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: July 2, 2024

Respectfully submitted,

POMERANTZ LLP

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